UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK

BEN-ZION KARMON,	
Plaintiff,	Case No
v.	
MIAMBE LTD.,	JURY TRIAL DEMANDED
Defendant.	

Plaintiff Dr. Ben-Zion Karmon ("Dr. Karmon" or "Plaintiff"), by and through his undersigned counsel, hereby brings this action for patent infringement under the laws of the United States relating to patents, 35 U.S.C. §§1 et seq., against Defendant Miambe Ltd. ("Miambe") hereby alleging as follows:

PARTIES

- 1. Dr. Karmon is an Israeli dentist, residing in Petach Tikva, Israel.
- 2. Dr. Karmon has been practicing dentistry for approximately 25 years, and is the inventor of 10 issued U.S patents in the field of dental implants and bone regeneration.
- 3. Upon information and belief, Defendant Miambe Ltd. is an Israeli company with an address of 40 Hanesiim Street, Petach-Tikva 4955042, and doing business in the United States as Miambe USA and/or Miambe LLC, a New Jersey Corporation, with a principal place of business in Fair Lawn, New Jersey (separately and collectively, "Miambe").

JURISDICTION AND VENUE

- 4. This Court has exclusive subject matter jurisdiction pursuant to 28 U.S.C. §§1331 and 1338(a) because this action arises under the patent laws of the United States.
- 5. Defendant Miambe is subject to the personal jurisdiction of this Court at least by committing acts of infringement in the State of New York, thereby establishing its legal presence within the State, including, without limitation, directly and indirectly selling and offering for sale to New York residents products that, when used according to Miambe's instructions, infringe the patent-in-suit.
- 6. Upon information and belief, Miambe has also generally acted to place these infringing products into the stream of commerce with the intent, purpose, and reasonably foreseeable result of supplying the New York market therewith.
- 7. At least by virtue of its above-described actions, Miambe has transacted business (as that term is construed under N.Y. C.P.L.R. §§301 and 302(a)(1) and (2)), performed services, contracted to supply services, caused tortious injury, regularly done or solicited business, engaged in a persistent course of conduct, and/or derived substantial revenues from infringing products used in New York.
- 8. In light of Miambe's aforementioned contacts with the State of New York and its purposeful availment of the rights and benefits of New York law, maintenance of this suit in this Court would not offend traditional notions of fair play and substantial justice.
- 9. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b), (c), and (d) and 1400(b) because, inter alia, a substantial part of the events or omissions giving rise to the claims occurred in this judicial district.

COUNT 1 INFRINGEMENT OF U.S. PATENT NO. 8,864,841

- 10. Dr. Karmon is the sole inventor of United States Patent No. 8,864,841 ("the '841 patent"), entitled "Method for Displacement of the Schneiderian Membrane," which was duly and legally issued by the United States Patent and Trademark Office on October 21, 2014. A true and correct copy of the '841 patent is attached hereto as Exhibit A.
- 11. Dr. Karmon is the owner of the '841 patent with all substantive rights in and to that patent, including the sole and exclusive right to prosecute this action and enforce the '841 patent against infringers, and to collect damages for all relevant times.
- 12. The application that issued as the '841 patent was published by the United States Patent and trademark Office on July 5, 2007 (the "Publication Date").
- 13. Miambe sells and offers to sell sinus lift kits for use in sinus augmentation procedures, and instructs customers on the use of its sinus lift kits.
- 14. Miambe has been and is now directly infringing and/or indirectly infringing the '841 patent by way of inducement and/or contributory infringement, literally and/or under the doctrine of equivalents in violation of 35 U.S.C. §271, including by selling a product with no substantial non-infringing use, and by actively inducing customers to infringe the '841 patent by performing a minimally invasive antral membrane balloon elevation sinus augmentation procedure covered by at least claims 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 14, 15, 16, 17, 18, 19, 20, 21, and 22 of the '841 patent.

<u>Infringement of Claim 1</u>

15. Independent claim 1 of the '841 patent recites: A method for displacing the Schneiderian membrane from the maxillary bone comprising: forming a path of insertion through the

alveolar ridge of said maxillary bone towards said Schneiderian membrane; inserting through said path of insertion a hollow cannula, said cannula has a distal portion and a proximal portion, at least part of said distal portion of said cannula being inside said alveolar ridge, said proximal portion of said cannula being proximally to said alveolar ridge, said cannula being part of a device, said device further includes an expandable inflatable container, an extension tube and injecting element, said container has a proximal portion and a distal portion, said proximal portion of said container being located adjacent said distal portion of said cannula, said extension tube has a proximal portion and a distal portion, said proximal portion of said extension tube being located proximally to said cannula, said proximal portion of said extension tube being connected to said injecting element; activating said injecting element to inflate through said extension tube said distal portion of said container so said distal portion of said container is expanded and advanced distally to the distal end of said cannula inside said maxillary bone to displace a segment of said Schneiderian membrane from a surface of said maxillary bone, said segment of said Schneiderian membrane was touching said surface before being displaced, at least part of said expanded distal portion of said container being between said displaced segment of said Schneiderian membrane and said surface, said surface is selected from the group consisting of the floor of the maxillary sinus and the floor of the nasal cavity.

16. Miambe's promotional materials, including instructions and clinical demonstrations and animations available on its website, www.miambe.com, (individually and collectively the "Miambe Instructional Material") instructs customers to use the Miambe device for displacing the Schneiderian membrane from the maxillary bone as recited in claim 1. The Miambe Instructional Material shows drilling through the alveolar crest until exposure of the antral membrane (called also the Schneiderian membrane), and inserting a metal sleeve cannula of a balloon-harboring device into the osteotomy. The Miambe Instructional Material shows that the Miambe device includes an injecting element, cannula, balloon (expandable inflatable container), connector, and extension tube,

and further instructs that the device is prepared by cutting the distal edge of the plastic tube (extension tube), connecting the plastic tube to an indeflator (injecting element), injecting saline with the indeflator until the saline emerges from the distal end of the plastic tube and connecting the balloon harboring device to the distal edge of the plastic tube. The Miambe Instructional Material further shows that the Schneiderian membrane elevation is controlled with the balloon by rotation of the indeflator until the desired elevation.

<u>Infringement of Claim 2</u>

- 17. Dependent claim 2 recites: "The method of claim 1, wherein the entire displaced Schneiderian membrane being free of perforations along the entire procedure.
- 18. The Miambe Instructional Material instructs verifying that the sinus membrane is free of perforation after forming the path of insertion, verifying that the membrane is free of perforation after inserting the cannula and expanding the container (balloon), evaluating membrane integrity after drilling by direct membrane visualization using a suction syringe, and evaluating membrane integrity after balloon removal, as recited in claim 2.

<u>Infringement of Claim 3</u>

- 19. Dependent claim 3 recites: The method of claim 2, wherein at least part of said proximal portion of said container being inside said distal portion of said cannula while said distal portion of said container being expanded distally to said distal end of said cannula.
- 20. The Miambe Instructional Material instructs that the balloon is inflated with the indeflator and verifying the balloon enters into the metal sleeve cannula such that at least part of the proximal portion of the balloon is inside the distal portion of the cannula while the distal portion of the balloon is expanded distally to the distal end of the cannula, as recited in claim 3.

<u>Infringement of Claim 4</u>

- 21. Dependent claim 4 recites: The method of claim 2, wherein said method includes the insertion of a dental implant through said path of insertion.
- 22. The Miambe Instructional Material instructs that the insertion of a dental implant through the path of insertion is recommended, as recited in claim 4.

Infringement of Claim 5

- 23. Dependent claim 5 recites: The method of claim 3, wherein at least part of said distal portion of said container being inside said distal portion of said cannula before being expanded, said at least part of said distal portion of said container being advanced outside said distal portion of said cannula.
- 24. The Miambe Instructional Material instructs that at least part of the distal portion of the balloon is inside the distal portion of the metal sleeve cannula before being expanded, and that at least part of the distal portion of the balloon is advanced outside the distal portion of the metal sleeve cannula, as recited in claim 5.

- 25. Dependent claim 6 recites: The method of claim 5, wherein said at least part of said distal portion of said container being advanced outside said distal portion of said cannula solely by the inflation of said container.
- 26. The Miambe Instructional Material instructs that at least part of the distal portion of the balloon is advanced outside the distal portion of the metal sleeve cannula by inflating of the balloon using the indeflator, as recited in claim 6.

<u>Infringement of Claim 7</u>

- 27. Dependent claim 7 recites: The method of claim 5, wherein the device further includes a connector, the connector has a proximal portion and a distal portion, said proximal portion of said connector being connected to said distal portion of said extension tube, said distal portion of said connector being connected to said proximal portion of said cannula.
- 28. The Miambe Instructional Material shows that the Miambe device includes a tube connector element, that the connector has a proximal portion and a distal portion, that the proximal portion of the connector is connected to the distal portion of the extension tube, and that the distal portion of the connector is connected to the proximal portion of the metal sleeve cannula, as recited in claim 7.

Infringement of Claim 8

- 29. Dependent claim 8 recites: The method of claim 7, wherein said proximal portion of said cannula has an internal thread, said distal portion of said connector has an external thread, said distal portion of said connector being screwed inside said proximal portion of said cannula.
- 30. The Miambe Instructional Material shows that in the Miambe device the proximal portion of the metal sleeve cannula has an internal thread, the distal portion of the tube connector element has an external thread, and the distal portion of the connector element is screwed inside the proximal portion of the metal sleeve cannula, as recited in claim 8.

Infringement of Claim 9

31. Dependent claim 9 recites: The method of claim 8, wherein the distal end of said connector being located proximally to the proximal end of said container.

32. The Miambe Instructional Material shows that the distal end of the tube connector element of the Miambe device is located proximally to the proximal end of the balloon, as recited in claim 9.

Infringement of Claim 10

- 33. Dependent claim 10 recites: The method of claim 3, wherein said activating of said injecting element is advancing a flowable material inside said container, said flowable material is passing through and touching said proximal portion of said container proximally to said distal end of said cannula.
- 34. The Miambe Instructional Material shows that inflation of the balloon in the Miambe device is performed using the indeflator (injecting element) and advancing a flowable material such as saline or contrast fluid inside the balloon, the flowable material passing through and touching the proximal portion of the balloon proximally to the distal end of the metal sleeve cannula, as recited in claim 10.

- 35. Dependent claim 11 recites: The method of claim 3, wherein said at least part of said proximal portion of said container being fixated inside said cannula during the entire surgical procedure.
- 36. The Miambe Instructional Material instructs that the balloon is inflated using the indeflator to verify integrity of the balloon when it emerges from the metal sleeve cannula, and further shows that at least part of the proximal portion of the balloon is fixated inside the metal sleeve cannula during the entire surgical procedure, as recited in claim 11.

- 37. Independent claim 14 recites: A method for displacing the Schneiderian membrane from the maxillary bone comprising: Forming a path of insertion through the alveolar ridge of said maxillary bone towards said Schneiderian membrane; inserting through said path of insertion a hollow cannula, said cannula being part of a device, said device further includes an expandable inflatable container, an extension tube and injecting element, at least part of said container being inside said cannula, said extension tube has a proximal portion and a distal portion, said proximal portion of said extension tube being located proximally to said cannula, said proximal portion of said extension tube being connected to said injecting element; activating said injecting element to inflate through said extension tube said container so said at least part of said container is expanded and advanced from inside said cannula to be distally to the distal end of said cannula inside said maxillary bone to displace a segment of said Schneiderian membrane from a surface of said maxillary bone, said segment of said Schneiderian membrane was touching said surface before being displaced, said surface is selected from the group consisting of the floor of the maxillary sinus and the floor of the nasal cavity.
- 38. The Miambe Instructional Material demonstrates that the Miambe device and method are intended for displacing the Schneiderian membrane from the maxillary bone as recited in claim 14. The Miambe Instructional Material shows drilling through the alveolar crest until exposure of the antral membrane (called also Schneiderian membrane), and inserting a metal sleeve cannula of a balloon-harboring device into the osteotomy. The Miambe Instructional Material shows that the Miambe device includes an injecting element (indeflator), cannula, balloon (expandable inflatable container), connector, and extension tube, and further instructs that the Miambe device is prepared by cutting the distal edge of the plastic tube (extension tube), connecting the plastic tube to an indeflator (injecting element), injecting saline with the indeflator until the saline emerges from the distal end of

the plastic tube and connecting the balloon harboring device to the distal edge of the plastic tube. The Miambe Instructional Material further shows that the Schneiderian membrane elevations is controlled with the balloon by rotation of the indeflator until the desired elevation, as recited in claim 14.

Infringement of Claim 15

- 39. Dependent claim 15 recites: The method of claim 14, wherein the entire displaced Schneiderian membrane being free of perforations along the entire procedure.
- 40. The Miambe Instructional Material instructs verifying that the membrane is free of perforation after forming the path of insertion, verifying that the membrane is free of perforation after inserting the cannula and expanding the balloon (expandable inflatable container), evaluating membrane integrity after drilling by direct membrane visualization using a suction syringe, and evaluating membrane integrity after balloon removal, as recited in claim 15.

<u>Infringement of Claim 16</u>

- 41. Dependent claim 16 recites: The method of claim 15, wherein said container has a proximal portion and a distal portion, said proximal portion of said container being inside said distal portion of said cannula while said distal portion of said container being expanded distally to said distal end of said cannula.
- 42. The Miambe Instructional Material instructs that the balloon is inflated with the indeflator and verifying the balloon enters into the metal sleeve cannula such that at least part of the proximal portion of the balloon is inside the distal portion of the cannula while the distal portion of the balloon is expanded distally to the distal end of the cannula, as recited in claim 16.

<u>Infringement of Claim 17</u>

- 43. Dependent claim 17 recites: The method of claim 15, wherein said at least part of said container being advanced outside said cannula solely by the inflation of said container.
- 44. The Miambe Instructional Material instructs that at least part of the balloon is advanced outside the metal sleeve cannula by inflating of the balloon using the indeflator, as recited in claim 17.

<u>Infringement of Claim 18</u>

- 45. Dependent claim 18 recites: The method of claim 15, wherein said device further includes a connector, said connector has a proximal portion and a distal portion, said cannula has a proximal portion and a distal portion, said proximal portion of said connector being connected to said distal portion of said extension tube, said distal portion of said connector being connected to said proximal portion of said cannula.
- 46. The Miambe Instructional Material shows that the Miambe device includes a tube connector element, that the connector has a proximal portion and a distal portion, that the metal sleeve cannula has a proximal portion and a distal portion, that the proximal portion of the connector is connected to the distal portion of the extension tube, and that the distal portion of the connector is connected to the proximal portion of the metal sleeve cannula, as recited in claim 18.

<u>Infringement of Claim 19</u>

47. Dependent claim 19 recites: The method of claim 18, wherein said proximal portion of said cannula has an internal thread, said distal portion of said connector has an external thread, said distal portion of said connector being screwed inside said proximal portion of said cannula.

48. The Miambe Instructional Material shows that in the Miambe device the proximal portion of the metal sleeve cannula has an internal thread, the distal portion of the tube connector element has an external thread, and the distal portion of the connector element is screwed inside the proximal portion of the metal sleeve cannula, as recited in claim 19.

Infringement of Claim 20

- 49. Dependent claim 20 recites: The method of claim 19, wherein the distal end of said connector being located proximally to the proximal end of said container, said proximal portion of said cannula being proximally to said alveolar ridge.
- 50. The Miambe Instructional Material shows that the distal end of the tube connector element of the Miambe device is located proximally to the proximal end of the balloon, and that the proximal portion of the metal sleeve cannula is proximal to the alveolar ridge, as recited in claim 20.

<u>Infringement of Claim 21</u>

- 51. Dependent claim 21 recites: The method of claim 14, wherein said activating of said injecting element is advancing a flowable material inside said container, said flowable material is touching said container proximally to said distal end of said cannula.
- 52. The Miambe Instructional Material shows that inflation of the balloon in the Miambe device is performed using the indeflator and advancing a flowable material such as saline or contrast fluid inside the balloon, the flowable material touching the balloon proximally to the distal end of the metal sleeve cannula, as recited in claim 21.

- 53. Independent claim 22 recites: A method for displacing the Schneiderian membrane from the maxillary bone comprising: Forming a path of insertion through the alveolar ridge of said maxillary bone towards said Schneiderian membrane; inserting through said path of insertion a hollow cannula, said cannula being part of a device, said device further includes an expandable inflatable container, an extension tube and injecting element, said container has a proximal portion and a distal portion, said proximal portion of said container being inside said cannula, said extension tube has a proximal portion and a distal portion, said proximal portion of said extension tube being located proximally to said cannula, said proximal portion of said extension tube being connected to said injecting element; activating said injecting element to advance a flowable material through said extension tube into said container so said flowable material is touching said proximal portion of said container inside said cannula, said distal portion of said container being expanded distally to the distal end of said cannula inside said maxillary bone to displace a segment of said Schneiderian membrane from a surface of said maxillary bone, said segment of said Schneiderian membrane was touching said surface before being displaced, said surface is selected from the group consisting of the floor of the maxillary sinus and the floor of the nasal cavity.
- 54. The Miambe Instructional Material demonstrate that the Miambe device and method are intended for displacing the Schneiderian membrane from the maxillary bone as recited in claim 22. The Miambe Instructional Material shows drilling through the alveolar crest until exposure of the antral membrane (The Schneiderian membrane), and inserting a metal sleeve cannula of a balloon-harboring device into the osteotomy. The Miambe Instructional Material shows that the Miambe device includes an injecting element (indeflator), cannula, balloon (expandable inflatable container), connector, and extension tube, and further instructs that the Miambe device is prepared by cutting the distal edge of the plastic tube, connecting the plastic tube to an indeflator, injecting saline

with the indeflator until the salineemerges from the distal end of the plastic tube and connecting the balloon harboring device to the distal edge of the plastic tube. The Miambe Instructional Material further shows that the elevation of the sinus membrane (Schneiderian membrane) is controlled with the balloon by rotation of the indeflator until the desired elevation, as recited in claim 22.

Active Inducement

55. Miambe actively induces dentists and other health-care professionals to infringe the '841 patent, by among other things, (a) selling, distributing, and/or offering to sell and distribute its sinus lift kits for use in sinus augmentation procedures according to its minimally invasive antral membrane balloon elevation procedure and system; (b) providing instructions for using such kits in practicing its minimally invasive antral membrane balloon elevation procedure; and (c) marketing, performing promotional activities and providing advertising for using such kits in practicing its minimally invasive antral membrane balloon elevation procedure. Miambe engages in the foregoing activities because it specifically intends that dentists and other health-care professionals use its sinus lift kits to perform its minimally invasive antral membrane balloon elevation procedure, which is covered by the '841 patent. Miambe thereby specifically intends dentists and other health-care professionals to infringe the '841 patent.

Contributory Infringement

- 56. Miambe also contributorily infringes the '841 patent because there is no substantial non-infringing use for its sinus lift kits.
- 57. Miambe has derived and received and will continue to derive and receive gains, profits, advantages and revenue from the aforesaid acts of infringement and sale of its sinus lift kits

and the third-party infringers' infringing activities in an amount that is not presently known to Dr. Karmon.

- 58. Miambe's infringing activities are without the consent of, authority of or license from Dr. Karmon.
 - 59. Miambe's infringement will continue unless enjoined by this court.
- 60. Dr. Karmon has been damaged as a result of the infringing conduct by Miambe alleged above and, thus, Miambe is liable to Dr. Karmon in an amount that adequately compensates Dr. Karmon for such infringements, which, by law, cannot be less than a reasonable royalty, together with interest and costs as fixed by this Court under 35 U.S.C. § 284.

Willful Infringement

- 61. Miambe has notice of the '841 patent, or the underlying patent application, since at least 2011. Accordingly, Miambe is also liable to Dr. Karmon for a reasonable royalty that adequately compensates Dr. Karmon for Miambe's infringements during the period between the Publication Date and the issuance of the '841 patent under 35 U.S.C. §154(d).
- 62. Miambe's infringements occurred and continue to occur with knowledge of and/or objective recklessness and thus has been and continues to be willful and deliberate. Miambe's willful and deliberate infringement entitles Dr. Karmon to enhanced damages under 35 U.S.C. §285.
- 63. This case is "exceptional" within the meaning of 35 U.S.C. §285, and Dr. Karmon is entitled to an award of attorneys' fees.

JURY DEMAND

Dr. Karmon hereby requests a trial by jury on all issues so triable by right.

DEMAND FOR RELIEF

Dr. Karmon requests that the Court find in its favor and against Miambe, and that the Court grant Dr. Karmon the following relief:

- a. Judgment that one or more claims of the '841 patent have been infringed, either literally and/or under the doctrine of equivalents, by Miambe and/or by others to whose infringement defendant has contributed and/or by others whose infringement has been actively induced by Miambe;
 - b. Judgment that Miambe's infringement has been willful;
- c. A permanent injunction enjoining Miambe and its respective officers, directors, agents, servants, affiliates, employees, divisions, branches, subsidiaries, parents, and all others acting in active concert therewith from infringement, inducing infringement of, or contributing to infringement of the '841 patent;
- d. Judgment that Miambe account for and pay to Dr. Karmon all damages to and costs incurred by Dr. Karmon because of Miambe's infringing activities including treble damages for willful infringement and other conduct complained of herein;
- e. That Dr. Karmon be granted pre-judgment and post-judgment interest on the damages caused by Miambe's infringing activities and other conduct complained of herein;
- f. That the Court declare this to be an exceptional case and award Dr. Karmon his reasonable attorney's fees and costs in accordance with 35 U.S.C. § 285; and
- g. That Dr. Karmon be granted such other and further relief as the Court may deem just and proper under the circumstances.

RESPECTFULLY SUBMITTED,

March 3, 2016

Daniel J. Melman

Daniel J. Melman

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